Canadian Environmental Advisory Council
Conseil consultatif canadien de l'environnement

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Listing Toxics Under CEPA — Is the Chemistry Right?

May 1988

Canada

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Listing Toxics Under CEPA - Is the Chemistry Right?

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Canadian Environmental Advisory Council | **Conseil consultatif canadien de l'environnement**

Ottawa, Canada
K1A 0H3

May 3, 1988

Honourable Tom McMillan, P.C., M.P.,
Minister of the Environment,
Ottawa

Dear Mr. McMillan:

The Canadian Environmental Advisory Council wishes to transmit for your consideration the enclosed report "Listing Toxics under CEPA - Is the Chemistry Right?" The purpose of the report is to discuss how toxic chemical lists can be developed and how toxics can be effectively regulated in Canada. Given the increasing scientific evidence of the hazards to life and the rising levels of public concern, we strongly urge the rapid implementation of the priority chemicals listing process. We believe that CEPA (The Canadian Environmental Protection Act) provides a critical opportunity for Canada to take the lead internationally in regulating toxic chemicals. Thus far the process has been rigid and agonizingly slow. But in making a fundamental change we encounter a basic challenge. The short term need for a list of chemicals must be balanced against the need for long term flexibility so the list may reflect the latest research and knowledge. Clear scientific criteria must be developed for the listing of the priority chemicals, and the regulations under CEPA must incorporate the requirement for bioassessment in the form of toxicological testing. Thus the list will be an evolving process. This area is one of the most difficult aspects of environmental regulation but one on which the credibility and public acceptance of CEPA rests.

We would be delighted to develop further any aspects of this report if it would be of service. In the meantime, we would request your permission to make this report available immediately to the Priority Substances Advisory Panel.

Sincerely,

Robert Page
Chairman

Canada

ROLE OF THE
CANADIAN ENVIRONMENTAL ADVISORY COUNCIL

The Canadian Environmental Advisory Council (CEAC) is a body representing a cross-section of Canadians who are knowledgeable about the environment. It operates in a confidential advisory capacity to the Minister of the Environment. It provides the Minister with an alternative to the advice provided by the Department of the Environment and other federal agencies, and to the advice of specific interest groups. Council's public role, in terms of activities such as the publishing of reports, is therefore secondary to its primary function of providing advice to the Minister of the Environment.

ACKNOWLEDGEMENTS

This report was prepared by the members of the Council led by Peter Chapman (Vancouver) and Doug Cook (Toronto). Membership is listed in Annex 1. The report incorporates, in part, material prepared by the individuals listed in Annex 2.

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EXECUTIVE SUMMARY

This report discusses the development of priority chemical lists for regulation under CEPA, and as such provides information that may be of use to those designing such lists, including in particular the Priority Substances Advisory Panel. However, assessment and regulation under CEPA will not be effective if based solely on single-chemical lists; this report also discusses the need to incorporate bioassessment into the regulations in the form of toxicological testing of chemicals, substances and environmental media of concern.

This report contains a number of recommendations; key among them are:

- The List, the related selection criteria, and the assessment process must be subject to peer review, be technically defensible, and the technical validity of how the List is used must be clear;

- The List of toxic chemicals must be criteria driven, and include a mechanism to add or remove compounds as appropriate;

- Broad-scale approaches to substance listings (i.e., including mixtures, emissions and effluents) must be realistic and based on measurable parameters;

- Possible environmental problems such as electromagnetic radiation which are not substances and are thus not included under CEPA need to be evaluated for inclusion;

- Certain classes of hazardous substances are treated by specific legislation outside of CEPA, and each province has its own environmental legislation. CEPA must have overriding authority in cases where legislation and regulation are not at least equivalent to CEPA;

- There may be organizational problems within and between the Departments involved in CEPA; strong integrative activities are required to ensure the smooth working and interrelationships between these Departments;

- Actions to be taken after the Toxic Substances Advisory Panel produce its List must be defined and the appropriate level of scientific and administrative expertise must be assigned to support CEPA;

- The credibility of CEPA depends on rapid action; present timing projections for substance assessment prior to regulation are not appropriate to the challenge;

- The effectiveness of CEPA requires periodic assessment to determine whether the pollution level in Canada in decreasing, increasing or holding steady;

- The Bruntland Commission's recommendations (economy-environment linkages involving sustainable development) must be an integral part of CEPA and of regulations promulgated under CEPA.

FOREWORD

In the fall of 1986, the Minister of the Environment released the Draft Environmental Protection Act for public review and consultation. The Canadian Environmental Advisory Council (CEAC) took part in this review by holding a workshop with current members and selected CEAC "alumni". The results of this workshop were published as a report, "Review of the Proposed Environmental Protection Act" (CEAC, 1987). Council made a number of recommendations in the report, one of which was to provide a "jump start" list of chemicals recognized as toxic and common in Canadian commerce. This suggestion was driven by frustration with the fact that, after 12 years under the Environmental Contaminants Act, only five chemicals or chemical groups had been scheduled for control. In marked contrast, other international, national and provincial jurisdictions (including elsewhere in Environment Canada itself) had scheduled, for surveillance or control, considerably longer lists of toxic chemicals common in commerce. To help the process along, Council prepared a draft list of toxic chemicals that could be included in the "jump start" Schedule I as part of the revised legislation.

Although the drafters of Bill C-74, the Canadian Environmental Protection Act, elected not to include a "jump start" list of toxic chemicals in the legislation, provision was made for work to begin immediately on identifying candidate chemicals that would be assessed for inclusion on the toxic chemicals priority list (i.e., Schedule I). This work is currently being carried out by the Priority Substances Advisory Panel appointed by the Minister specifically for this task.

This CEAC report is intended to supplement Council's earlier report, and to provide another source of information for the Priority Substances Advisory Panel. Specifically, our report discusses the need for both short-term (a list of toxic chemicals) and long-term measures (including a combination of chemical and bioassessment approaches) to assess and regulate toxic chemicals under CEPA.

There is every reason for Canada to act swiftly to list and regulate by developing standards immediately, but it is equally important that the correct standards be developed. Canada is behind some other jurisdictions in this regard. We believe that if the Federal Government runs fast with CEPA, Canada may well reach a position of leadership, nationally and internationally.

It is our perception that Canada is viewed in the international forum with respect for its concern about environmental quality, especially where actions of one nation have adverse effects on another. Canada can become an international "environmental quality broker"; it posseses a credible, sound environmental science base which could speak with intellectual authority on the international scene.

But first, the Federal Government must promulgate CEPA and proceed vigorously, expeditiously, correctly and appropriately to list toxic chemicals in the schedules, apply thoughtful and forceful regulations, and set an example nationally and internationally. This will raise the subsequent and intellectually more challenging task of devising strategies and mechanisms by which new and existing toxic chemicals are controlled from "cradle to grave" and "virtually eliminated" from the environment. We hope that this report will be a small first contribution to that process.

INTRODUCTION

In the 1960's and 1970's, it was realized that the air, water, soil, and sediment environments and their biota had become contaminated to various degrees with a large number of chemicals of anthropogenic origin. Governments subsequently faced the task of identifying, assessing and controlling or regulating those chemicals which were observed to be, or were suspected to be, present in these environmental media. The logical initial step was to list those chemicals which are observed to be present in the environment. This list tended to grow continuously because, as analytical methods improved, the numbers of chemicals detected increased, albeit at smaller and smaller concentrations. Most emphasis was placed on chemicals of industrial or commercial origin and on agricultural chemicals, i.e., insecticides, herbicides, fungicides, rodenticides and bactericides.

Several transportation accidents involving commercial chemicals resulted in increasing concern about the safety of transportation of chemicals through populated areas. Increasing scrutiny was directed to the safe handling of these chemicals and to the designation or listing of chemicals which, under the Transportation of Dangerous Goods Act, were perceived to be "dangerous goods". Industrial accidents, such as the incident at Bhopal, resulted in assessments of the presence and prevalence of chemical synthesis intermediates and products which may be inadvertently released to the environment in accidents or in air or water effluents. Investigations of the natural environment have raised suspicions about adverse effects of chemicals such as the freons on the ozone layer. As an example, some incinerators have been found to emit dioxins. Some chemicals such as mercury undergo unexpected chemical changes rendering them more toxic.

In short, there has been a growth in media coverage about "toxic chemicals", reflecting a sincere concern among the public and scientific communities that our management practices are inadequate, and that perhaps the health of humans and the environment is being unnecessarily placed at risk (State of the Environment Report, 1986). The resulting concern has become translated into legislative responses such as CEPA.

There is no doubt whatever about the need for listing those chemicals that are toxic. Anyone familiar with the issue could, given time, prepare dossiers documenting physical, chemical and toxicological properties. Material from other jurisdictions can be copied. The National Research Council of Canada has already done this for many chemicals, as has Environment Canada in its TIPS (Technical Information on Problem Spills) manuals. In some cases there are entire text books on specific substances. There are annual conferences on some chemical classes, such as the dioxins. Occupational restrictions apply to many chemicals.

Care must be taken, however, to ensure that chemical contamination (measured levels of chemicals in the environment) is not confused with chemical toxicity (actual effects of chemicals in the environment). Toxic effects can be the response to a single chemical (justifying single-chemical lists), or the response to a complex mixture of chemicals (which may demonstrate syngergistic and/or antagonistic interactions), or to chemical(s) unknown. In neither of the latter two cases are single-chemical lists sufficient for assessment and regulation. The point is, it is the toxic effects that count; it does not matter how elevated the levels of any particular chemical, group or combination of chemicals in the environment, unless they exert an effect. Toxics control under CEPA cannot be based solely on single-chemical lists but must also involve bioassessment including toxicological testing.

As discussed in this report, we regard chemical-by-chemical listing as necessary under CEPA as it represents the intention to "anticipate and prevent", making use of existing information for predictive purposes. However, there is a need to include bioassessment, to direct where "react and cure" effort must be expended, as well as to provide more rigorous predictive information for future environmental protection purposes.

CEAC decided to write this report for three reasons. First, we feel that there is a need to emphasize that any and all lists of toxic chemicals promulgated under CEPA be of legal value, technically defensible, applicable to the correct environmental media, and "alive" (i.e., that a mechanism exists to add or delete chemicals as new information becomes available). Second, we are convinced that assessment and regulation under CEPA will not be effective if based solely on single-chemical lists; there is a need to incorporate bioassessment into the regulations in the form of toxicological testing of chemicals, substances and environmental media of concern. Third, we have a number of concerns related to the short- and long-term process that we feel need to be addressed.

CURRENT APPROACHES - DEVELOPING LISTS OF CHEMICALS

Background

Currently, there are over 60,000 chemicals being used in commerce around the world, some 30,000 of these in Canada. The number of chemicals of possible concern run to about 1500. There are now numerous lists of chemicals, but there is considerable variation in the content of the lists. It is not possible to specify an exact number of chemicals. Some inorganic chemicals ionize in contact with water and thus lose their initial identity. Some lists name PCBs (polychlorinated biphenyls) as one chemical, others as six groups of chemicals, whereas in reality, the PCBs consist of 209 possible individual chemicals. It is only recently that analytical chemists have been successful in identifying all 209 congeners. Many chemicals, such as surfactants and solvents, are complex mixtures which are difficult to analyze. One designation, such as "naphtha", may represent 1000 chemicals. For legislative purposes, most jurisdictions have established from these "raw" lists, smaller lists of "priority" chemicals. These are chemicals which are usually observed in the environment, are known to have the potential to cause adverse ecological/biological effects, and are thus believed to be worthy of control and regulation.

The first and most celebrated list was the U.S. Environmental Protection Agency's Priority Pollutants list, or EPA list, which originally included 129 chemicals or groups. This list was established as a result of a legal agreement between the U.S. EPA and the Natural Resource Defence Council in 1976. International organizations, such as OECD, have established somewhat similar lists, as has the Canadian Federal Government under the Environmental Contaminants Act. It also has a list of "frequently spilled" chemicals compiled by the Environmental Emergencies Branch. The State of Michigan has a Critical Materials Register, which is an expansion of the EPA list. The International Agency for Research on Cancer (IARC) produces a list of chemicals suspected to be carcinogenic. The United Nations Environment Programme has an International Register of Potentially Toxic Chemicals (IRPTC) and issues a regular bulletin describing international developments in toxic chemical assessment. Agencies concerned with particular ecosystems, such as the North American Great Lakes, have established lists of chemicals found throughout that ecosystem, an example being an International Joint Commission Inventory of Chemicals Identified in the Great Lakes System. There are also lists of chemicals found in specific parts of ecosystems, for example, the Niagara River Toxic Chemical list.

In Canada, the most comprehensive and thoughtfully prepared list is the Province of Ontario's Effluent Monitoring Priority Pollutants List, which consists of 180 chemicals or groups which have been identified as being of particular concern to that Province.

Developing Lists of Chemicals for CEPA

It is a challenging task to select from "raw lists" of chemicals a smaller manageable number of "priority" chemicals. Such chemicals will receive more intense scrutiny, analytical protocols will be developed, properties and toxicity measured, and reviews conducted of sources, fate, and effects. This selection contains an element of judgement and is approached by different groups in different ways. A common thread to many of these

selection processes is the consideration of five factors: quantity, persistence, bioaccumulation, toxicity, and a miscellaneous group of "other adverse effects".

Quantity

The first factor is the quantity used or transported, including consideration of the fraction of the chemical which may be discharged to the environment during use. Some chemicals, such as benzene, are used in very large quantities in fuels, but only a small fraction, (possibly a percent or two), is emitted into the environment through incomplete combustion or leakage during storage. Other chemicals, such as pesticides, are used in much smaller quantities, but are discharged totally and directly into the environment, ie., 100% is emitted. On the other extreme are chemical intermediates which may also be produced in large quantities, but are emitted in only minuscule amounts, except during an industrial accident. It is very difficult to compare the amounts emitted from these various categories, because they are highly variable and episodic. However, it is essential to consider this factor because there is a vast number of toxic chemicals which have no real adverse impact because they enter the environment in negligible quantities.

Persistence

The second factor is the chemical's environmental persistence, which may also be expressed as a lifetime, half-life, or residence time. Some chemicals, such as DDT or the PCBs, may exist in the environment for a period of 3-5 years by virtue of their resistance to transformation or degrading processes of biological and physical origin. They have the opportunity to migrate widely throughout the environment and reach vulnerable organisms. Their persistence results in the possibility of establishing relatively high concentrations. This arises because the amount in the environment (kilograms) can be expressed as being the product of the emission rate into the environment (kilograms per year) and the residence time of the chemical in the environment (years).

This is the same equation which controls a human population. For example, the number of Canadians, (about 25 million) is determined by the product of the rate at which Canadians are born (about 1/3 million per year), and the lifetime of Canadians (about 75 years). If Canadians only lived for 30 years, the population would drop to 10 million.

Intuitively, the amount and hence the concentration of a chemical in the environment must control the effect of that chemical in that environment since toxic effects generally respond to concentrations. Unfortunately, it is quite difficult to estimate the environmental persistence of a chemical. This is because the rate at which chemicals degrade depends on which environmental media they reside in, on temperature (which varies diurnally and seasonally), on incidence of sunlight which varies similarly, on the nature and number of degrading microorganisms which may be present, and on other factors such as acidity and the presence of catalysts. This varied persistence is in contrast to radioisotopes which have a half life which is fixed and unaffected by the media in which they reside. It is clear that long-lived chemicals such as PCBs are of much greater concern than those, such as phenol, which may persist in the aquatic environment for only a few days as a result of susceptibility to biodegradation. Some estimate of persistence or residence time is thus necessary for priority setting purposes. Organo-chlorine chemicals tend to be very persistent and thus are frequently found on priority lists.

Bioaccumulation

The third factor is bioaccumulation potential (i.e., uptake by organisms). This is a phenomenon, not an effect. Thus bioaccumulation per se is not of concern; bioaccumulation such that toxicity results (to the affected organism or to a predator on that organism) is of concern.

Some chemicals, notably the hydrophobic or "water-hating" organic chemicals, partition appreciably into organic media and establish high concentrations in fatty tissue. PCBs may achieve concentrations (i.e., they bioconcentrate) in fish at factors of 100,000 times the concentrations in the water in which the fish dwell. For a very few chemicals (notably PCBs, mercury, DDT) there is also a food chain effect in which small fish are consumed by larger fish at higher trophic levels and by other animals, such as gulls, otters, mink, and humans. These chemicals may be transmitted up the food chain and in doing so may experience an increase in concentration such that they are biomagnified.

Bioaccumulation tendency is normally estimated using an organic water partition coefficient and, more specifically, the octanol-water partition coefficient. This, in turn, can be related to the solubility of the chemical in the water. Clearly, chemicals which bioaccumulate, bioconcentrate and biomagnify have the potential to cause unusual toxic effects, can travel unusual pathways, and can exert severe toxic effects, especially on organisms at higher trophic levels.

Toxicity

The fourth factor is the toxicity of the chemical. The simplest manifestation of toxicity is acute toxicity. This is most easily measured as a concentration which will kill 50% of a population of an aquatic organism, such as a fish or an invertebrate (e.g., Daphnia magna), in a period of 24-96 hours, depending on test conditions. When the concentration which kills (or is lethal to) 50% (the LC50) is small, this corresponds to high toxicity. The toxic chemical may also be administered to laboratory animals such as mice or rats, orally or dermally. The results are then expressed as a lethal dose to kill 50% (LD50) in units of mg chemical/kg body weight of the animal.

More difficult, expensive and contentious are chronic, or sub-lethal tests, which assess the susceptibility of the organism to adverse effects from dosages or concentrations of chemicals which do not cause immediate death, but may lead ultimately to death. For example, the animal may cease to feed, be unable to reproduce, become more susceptible to predation, or display some abnormal behaviour which ultimately affects its life span or performance. The concentrations or dosages at which these effects occur are often about 1/10th to 1/100th of those which cause acute effects. Ironically, in many cases the toxic agent is an essential nutrient, i.e. too much or too little may cause adverse effects. As is frequently noted "the dose makes the poison".

Most difficult is the issue of genotoxicity, including carcinogenicity, mutagenicity, and teratogenicity. In recent years, a battery of tests has been developed in which organisms, ranging from microorganisms to mammals, are subjected to exposure to chemicals in an attempt to determine whether these chemicals can influence genetic structure or cause cancer. The principal difficulty is that these effects may have long latent periods, perhaps 20 to 30 years in humans. It is very difficult to extrapolate from the results of short term laboratory experiments to establish reliably the presence and magnitude of hazard to humans.

There may be suspicions that such a chemical may be producing cancer in perhaps 0.1% of a large human population over a period of perhaps 30 years, an effect which is very difficult (or probably impossible) to detect in epidemiological studies. But the premature death of 300 Canadians per year from such a cancer is cause for considerable concern. A major difficulty is that humans are voluntarily and involuntarily exposed to a large number of toxic chemicals including those derived from smoking, legal and illicit drugs, domestic and occupational exposure as well as environmental exposure. Despite these difficulties, a considerable number of chemicals have been assessed as being carcinogenic, mutagenic, or teratogenic, and it is even possible to assign some degree of potency to each chemical. Such chemicals usually rank high in priority lists.

Other Effects

Finally, there is a variety of other adverse effects which are of concern, some of tremendous ecological importance. These include:

- the ability to influence atmospheric chemistry (e.g., freons);
- alteration in pH (e.g., acid rain);
- unusual chemical properties such as chelating capacity which alter the availability of other chemicals in the environment;
- interference with visibility;
- odour (e.g., from organo-sulfur compounds);
- colour (e.g., from dyes); and,
- the ability to cause foaming in rivers (e.g., detergents or surfactants).

Selection Procedures

The most common selection procedure involves scoring each of the above factors on some hazard scale, for example 1-10. The factors may then be combined in an overall factor to assess priority. This is a subjective process and becomes difficult for two major reasons.

First, chemicals of quite different use patterns are difficult to compare. For example, chemical X may be produced in very large quantities, is emitted directly into the environment and is found in substantial concentrations in the environment, but is not believed to be particularly toxic. Examples are solvents such as trichlorethylene or plasticizers such as phthalate esters. On the other hand chemical Y may be produced in minuscule amounts but is very toxic, an example being the dioxins. Which deserves the higher priority?

Second, it appears that the adverse effects suffered by aquatic organisms and other animals, including humans, are the result of exposure to a large number of chemicals, and not just to one or two chemicals. Thus, assessing chemicals on a case by case basis may obscure the cumulative effect of a large number of chemicals. For example, if an organism is exposed to 150 chemicals, each at a concentration which is only 1% of the level which will cause death, then death is very likely to occur, but it cannot be attributed to any one of

these chemicals. It is the cumulative effect which causes death. The obvious prudent approach is to reduce exposure to all chemicals to the maximum extent possible. The issue is further complicated by the possibility that some chemicals will act synergistically, i.e., produce an effect which is greater than additive, or antagonistically, that is, the combined effect is less than additive.

The result is that there will probably be cases in which we are unable to prove that a specific chemical causes toxicity, but in reality it does contribute to an overall toxic effect. Indeed some believe that this situation will be the rule rather than the exception. Hence there is a real need to include bioassessment in the regulations. In other words, there is a requirement for bioassay testing in which organisms are exposed to mixtures of chemicals and/or to environmental media (e.g., air, water, effluent, soil, sediments) containing such mixtures. Such testing may be either environmental (where the main concern is the environment including Man) or medical (where the main concern is Man).

If it is assumed that chemicals are guilty until proven innocent, the prudent course of action would be to cast a fairly wide net of suspicion (i.e., assemble a fairly large list of chemicals) then work to elucidate sources, fate and effects with the aim of avoiding excessively punitive measures on the innocent. There is a danger that casting a narrow net will trap a few culprits, but the problem will not be solved. Or, by analogy, if the top 50 criminals in Canada are incarcerated, will this solve the crime problem? The philosophy of the excellent Environment Canada "Cradle to Grave" Report was essentially to reduce exposure to all chemicals by proper management. We may be over-zealous in some cases, but it is hoped that the cost or disruption need not be excessive. There are "checks and balances" in the system already. For example, industry will intervene forcefully if it believes it is being excessively regulated.

In our judgement, assessment or priority setting by scoring systems, (7 points for a carcinogen, 4 for bioaccumulation, etc.) should be regarded as a stop-gap measure which is forced upon us by our present inability to understand completely the dynamics and toxicity of chemicals in the environment. Ultimately, the correct approach must be to establish procedures by which the concentrations of chemicals in various environmental media can be estimated from a knowledge of the way in which a chemical is used (quantities used, fraction emitted into the environment), the environmental fate, persistence, the migration pathways of the chemical and the distribution of concentrations. The estimated concentrations, or distributions in concentration, can be used in two ways.

First, they can be compared with concentrations which are known to cause adverse effects, for example, with acute toxicity levels or levels suspected to cause a 1 in a million probability of cancer. A chemical which may exist in the environment at a concentration of 1/10th of the LC50 is clearly of higher priority than one which exists at a concentration of 1/100 of the LC50. If we can obtain both data on concentrations known to cause certain effects, and observed or calculated environmental concentrations, it is possible to calculate a quotient or ratio of these numbers which is a reliable indicator of priority. It is hoped that the quotient or "safety factor" will be large, i.e. the "effect" concentration is a large multiple of the environmental value. Most difficult and contentious is the treatment of cancer risk because of uncertainties in the "effect" concentrations.

Second, the environmental concentrations can be used to estimate total exposure of humans and other organisms to specific chemicals by air inhalation, drinking water, food ingestion, and dermal contact. It then becomes clear which media contribute most exposure;

if it is deemed desirable to reduce exposure, the most effective remedial strategy becomes apparent. As a simple example, this strategy could involve an advisory not to eat fish or drink water. There is a view that ultimately such "total exposure assessments" may be linked to pharmacokinetic models describing the fate of chemicals within the body and which enable organ concentrations to be calculated. These "internal exposures" or "delivered doses" are likely to be much more reliable indicators of adverse effect than external exposure or dose. Regrettably, this assessment and modelling capability is still in its infancy, but it is a goal worth striving towards.

THE PROCESS OF REGULATING TOXIC CHEMICALS UNDER CEPA

Development of a list is not sufficient by itself. Lists are "distorted" by analytical capabilities; there are problems in analyzing specific chemicals which may consequently be omitted from certain lists. Although a concerted effort to improve environmental analytical ability would be useful, you can't regulate what you can't measure.

The concept of Canada following a single-chemical approach, presumably leading to some sort of regulatory criteria, is reasonable in terms of products on the marketplace, but it is not reasonable in most cases in the real environment where complex mixtures are commonly found and where interactive effects are expected. Moreover, the analytical window available with today's technology, though ever-expanding, is equipment limited and not all-encompassing.

Chemical-specific approaches, when used in environmental studies, suffer from the possibility that observed biological effects are due to unmeasured, covarying chemicals. If the covariance is exact, then the measured chemicals can be considered as "indicators" of the unmeasured chemicals. However, if the covariance is inexact (i.e., the chemicals only covary some of the time or under certain circumstances), then the chemical-specific approaches will not address toxicity by unmeasured chemicals. Bioassessment, involving toxicological criteria, is a necessary component and complement to chemical lists as such criteria do not depend on extrapolation from single chemical responses, but rather derive real-world information. Such criteria could be based on bioassay testing, using the very valid philosophy that concerns should be based on documented biological effects.

Specific advantages of single-chemical and toxicological criteria are provided below. Since single-chemical approaches may be overly protective in some cases and under protective in others, combining the two approaches provides the best means of assuring a reasonable level of environmental protection.

Single-Chemical

Advantages

1. These criteria would be easy to apply.

2. They would require no specialized biological, chemical or other expertise.

3. They would be amenable to modeling approaches.

Disadvantages

1. No allowance can be made for chemical interactions within complex chemical mixtures (e.g., synergism, antagonism) or for unmeasured toxic contaminants. For instance, synergism may result in toxicity even though all individual chemical concentrations are below levels that would individually produce a biological effect.

2. It is unlikely that criteria can or will be developed for all chemicals of concern.

3. There may be little flexibility or adaptability in the established criteria values.

Toxicological (i.e., Bioassay Testing)

Advantages

1. Allowance, based on organism responses, is made for chemical interactions within complex chemical mixtures (e.g., synergism, antagonism) and for unmeasured toxic contaminants.

2. Minimum extrapolation is required.

3. These criteria would have substantial flexibility and adaptability; they would allow for aggressively attempting to find problems in the environment and back-tracking to the source.

4. They can be used with any chemical contaminant and do not require a priori assumptions concerning the specific mechanism for interactions between organisms and toxic contaminants.

Disadvantages

1. Extensive biological and chemical expertise will be required in implementing these criteria.

2. It will be difficult if not impossible to establish the cause(s) of any observed biological effects, particularly given natural variability and differences between laboratory and field situations.

A suggested strategy for use of combined single-chemical and toxicological criteria is provided in Table 1, using the example of an effluent discharge. In this example, chemical analyses are used as an initial screen, with bioassay testing used as an adjunct to the chemistry. These roles are often reversed, with bioassay testing used as the initial screen. Uses of bioassays are described below.

Bioassays primarily provide information on the toxicity of contaminated media (water, air, soil, tissue) by measuring the level of their effect on test organisms. Such information is necessary for regulation, monitoring and research purposes. There are two general ways in which bioassays can be used for regulation. First, they can be used to determine the relative toxicity of tested media to determine maximum or unacceptable toxicity for remedial action. In this context, bioassays often serve as the initial step in a tiered approach to assessment, which may ultimately include measures of sediment chemistry and in situ effects. Second, bioassays can be used as part of permitting programs to determine the acceptability of wastes for disposal, emission or discharge into the environment.

TABLE 1

EXAMPLE STRATEGY FOR COMBINING CHEMICAL LISTS AND TOXICOLOGY (BASED ON AN EFFLUENT DISCHARGE)

Preliminary Research:

1. Characterize samples using a literature search to determine their expected chemical composition.

2. Conduct multi-component analyses on a limited number of samples. Direct the analyses based on the expected composition, and also test that the expected is the reality.

3. Use literature and analytical information, together with the CEPA list of toxics of concern to short-list specific chemicals of concern.

Establishment of Monitoring:

4. Determine the variability in concentrations in the short-list of chemicals established in 3., above. Do so over a fixed period to be determined based on site-specific environmental characteristics (e.g., one month, monthly, a year).

5. Use bioassay testing to determine the toxicity of a limited number of samples.

6. If appropriate, conduct additional bioassay testing to determine relationships between toxicity and chemical composition, i.e., sources of toxicity.

Monitoring:

7. Conduct compliance monitoring on a realistic short-list of chemicals, and conduct synoptic bioassay testing.

Bioassays can be used in monitoring to determine long-term temporal or areal changes in toxicity, particularly after a management or engineering action such as the removal of a point source or treatment upgrading. Such information provides a direct measure of the effectiveness of management actions.

Finally, and as an integral part of both regulation and monitoring, bioassays can be used in research into fundamental questions of ecosystem degradation and recovery. For instance, bioassays can be used to determine which particular components of complex contaminant mixtures are responsible for observed toxic effects, both in laboratory studies and in analyses of field data.

RECOMMENDATIONS

Two types of recommendations are provided: short-term, related to the immediate requirement for a list of toxics under CEPA; and long-term, related to what comes next. Our recommendations are directed to the fact that regulatory action should be aimed at those chemical contaminants that are really causing problems, the environmental media where such problems are occurring, and guard against any unsuspected environmental insults.

Short-Term

A list of 50 substances for assessment as candidate Priority I substances is presently being prepared for CEPA by the Priority Substances Advisory Panel. CEAC endorses the need for such a list, but we suggest that 50 is the start-up and not a magic number. We offer the following comments concerning the development of a list of toxic chemicals under CEPA:

1. The Toxic Substances Advisory Panel must provide a manageable short-list for assessment. The List may be divisible into two types of substances, those of unquestionable environmental concern requiring immediate regulation, and those of questionable concern requiring further study.

2. The List must be criteria driven. Set criteria for inclusion/exclusion must be developed a priori. Such criteria should include: exposure (e.g., such factors as the areal and temporal extent of effects, persistence and transport parameters); ecological and biological effects (e.g., toxicity and genotoxicity); level of regulatory and other control measures.

3. Listings must be reversible/flexible. A mechanism needs to be developed to keep any list "alive", i.e., to add or remove compounds as appropriate. This would include a sunset clause.

4. The List, the related selection criteria, and the assessment process must be subject to peer review, such that they incorporate a high degree of scientific rigor.

5. The List, the criteria, and the assessment process must be technically defensible. There must be adequate justification for all aspects of the List. The environmental media of concern and of non-concern must be specified. Such media would include: air, water (fresh, salt, brackish), soil, sediment, tissue, food, humans. The List should not be confined to single chemicals but should also have provision for the inclusion of chemical groups as appropriate.

6. The technical validity of how the List is used must be clear. The List must provide protection for the environment, but without being overly protective such that neither is innovation in, for example, the chemical industry inhibited, nor is society deprived of beneficial chemicals.

7. The credibility of CEPA depends on moving rapidly to assess the chemicals recommended by the Priority Substances Advisory Panel, and to regulate as necessary and appropriate.

Rapid action is particularly necessary if a priority short-list within the 50 chemicals is recommended. Present projections of assessing 5 of the 50 compounds yearly are not appropriate to the challenge. Sufficient funds and authority must be allocated to perform the assessments in a timely manner (for elaboration on this point, see Annex 3).

8. Regulation should not proceed without clear and technically defensible rationale and criteria. The criteria used for determining substances for regulation must be very tight, even if those used to determine the initial list of approximately 50 substances for assessment is not. We recommend that, for each chemical listed under CEPA, chemical summaries be prepared based on set criteria and including the information shown in Table 2.

9. Similarities between individual chemicals can be used to list and regulate chemicals on a class rather than an individual basis. The basis for classes of chemicals, if such are combined to form single substances, needs to be appropriately defined. If the broad-scale approach is taken to substance inclusion (e.g., including mixtures, effluents and emissions), it must be put in realistic terms. For instance, there is no point in lumping different mixtures, effluents or emissions for which the components and toxicity are highly variable. If such are of concern, assessment is needed to determine problem components, which must be measurable.

Long-Term

CEPA is one of the most powerful environmental instruments that Canada has ever had; it provides the policy framework for promulgating biological standards into regulations, i.e., bioassessment. We strongly recommend such promulgation of biological standards. We also offer the following suggestions concerning long-term aspects of CEPA:

1. Substances are presently very broadly defined by CEPA. Strong integrative activities will be required by both the Departments of Environment, and Health and Welfare to ensure integrative substance evaluations and assessments so that all of the human and environmental concerns and factors are addressed in an adequate manner.

2. Decisions need to be made concerning what happens after the Toxic Substances Advisory Panel produces its list. As part of such decisions, some mechanism needs to be set in place to keep the list "alive". There is a need for advisory panel(s) for CEPA, in particular for the toxics list, to continue the process and advise on the final products, including in particular the principles of regulation under CEPA.

3. The Department of the Environment needs to ensure that it has both the qualified staff and the scientific expertise available to support CEPA. Moreover, the level of administrative capability for CEPA in both responsible Departments should be appropriate to the importance of this Act (c.f. Short-Term Recommendation 7).

4. Some potentially toxic agents such as noise and electromagnetic radiation are not included in CEPA because they are not substances. Similarly, biologicals such as hospital waste and biotechnology products are not adequately dealt with under CEPA. The problem of such exclusions should be investigated, and the Act amended as necessary and appropriate.

TABLE 2

OUTLINE FOR CHEMICAL SUMMARY INFORMATION

Chemical Name:
Synonyms:

General Description:
(Appearance, Physical/Chemical Data, Related Substances)

Transport Parameters:*
(General Behavior, Distribution and Mobility [Speciation, Solubility, Precipitation, Sorption/Desorption, Partition Coefficent, Degradation and Hydrolysis Rates, Organ Specificity, Tissue Elimination Rate, Degradation Products, Volatilization and Hydrolysis Rates])

Toxicity Parameters:*
(Relative Toxicity, Sensitive Organisms, Acute/Chronic Toxicity, Carcinogenecity/Mutagenicity/Teratogenicity, Human Cancer Risk [Daily Intake Limit])

* Must differentiate environmental media (i.e., air, water [fresh, salt, brackish], soil, sediment, tissue).

5. Certain classes of chemicals which are hazardous are treated by specific legislation outside of CEPA. These include radioactive materials, pharmaceuticals, food additives, cosmetics, pesticides, explosives, and combustible materials which are widely transported, including compressed and liquified gas. CEPA should have overriding authority if such legislation is not as effective as CEPA.

6. CEPA's applicability to the provinces, which have a wide variety of different environmental regulations, is unclear. The principles of harmonization and equivalency need to be applied to this problem. CEPA should have overriding authority if provincial regulations and legislation are inadequate. Federal-provincial consultations need to continue on this subject.

7. Canada must be in balance with overall world environmental requirements; current global needs require the use of both chemical and bioassessment protocols in regulation under CEPA and ensuring a proper scientific, social and economic basis for CEPA. The continuing process must be based on good science as directed by social and economic considerations, including proper implementation of the "nuts and bolts" of assessment and regulation, such as proper Quality Assurance/ Quality Control.

8. The effectiveness of CEPA itself requires assessment. Indicators need to be developed to determine whether CEPA is working, in other words, is the pollution level decreasing? Such should be determined and documented through regular state of the environment reporting.

9. It is not clear how the recommendations of the Bruntland Commission (economy-environment linkages involving sustainable development) will fit into regulations under CEPA (cf. Short-Term Recommendation 6). Clarification of this point is required. The guiding philosophy of the WCED, sustainable development by anticipating and preventing environmental deterioration, should inform both the short-term and long-term goals of CEPA.

ANNEX 1

MEMBERSHIP
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ANNEX 2

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ANNEX 3

EXTRACT FROM CEAC'S REVIEW OF THE PROPOSED ENVIRONMENTAL PROTECTION ACT (p. 20 AND 22)

2) Resources and Science

It must be appreciated that implementation of the proposed Act will require allocation of considerable resources for both management and scientific activities.

The Commercial Chemicals Branch of Environment Canada will require expansion to ensure that the Schedules are compiled within a reasonable length of time. Requirements for assessment and response to new chemical notifications will be ongoing, as will activities relating to the addition or deletion of chemicals from Schedules. The chemical assessment process will be a particularly demanding task not only in staff time but in the type of highly qualified person who will be required to make judgments on chemical release, exposure and toxic effects.

The Council notes that the United States Environmental Protection Agency's New Chemicals Program involves some 200-300 persons. Unfortunately, confidentiality considerations will frequently prevent information gained in the United States from becoming available to Environment Canada. In any event, the responsibility for protecting Canada's environment is Canadian, and there must be strong national commitment to conduct independent assessments.

We point out the following implications:

(i) The proposed Act will require individuals with a range and breadth of qualifications and experience ranging from knowledge of industrial chemistry to knowledge of environmental dispersion, exposure analysis, and toxicology. Such people are in short supply in Canada. Steps should be taken to increase the "pool" of scientific personnel within Environmental Canada that can be called upon to participate in this process.

(ii) The science of chemical exposure assessment and toxicity evaluation is still developing. It is essential that Environment Canada be at the forefront of this process by nourishing scientific efforts in this area, both within Environment Canada and through extramural funding.

(iii) Allocation of sufficient person years to the administration of the proposed Act will be essential.

(iv) This allocation should not result in the attrition of other Environment Canada programs such as research in the Canadian Wildlife Service, Atmospheric Environment Service or Great Lakes programs.

(iv) This allocation should not result in the attrition of other Environment Canada programs such as research in the Canadian Wildlife Service, Atmospheric Environment Service or Great Lakes programs.

It would be intolerable if Environment Canada could not administer the Act because of its inability to provide the required quantity and quality of intellectual resources. Environment Canada staff must be at least as knowledgeable and experienced in the science of "environmental toxicology" as those in industry who will introduce new chemicals. We call attention again to the concerns that the Council has repeatedly expressed in recent years about the continuing erosion of the scientific programs and scientific staff within Environment Canada.

3) Timing

The Council has serious concerns about the length of time that could be involved in making this proposed Act operational. The following are recommendations that may help expedite this process:

(a) Include the expanded Schedule IV, given above, in the final text of the proposed Act delivered to Parliament.

(b) Expand the resources of scientifically trained environmental chemists and ecotoxicologists in Environment Canada through new-hires. This should include senior, internationally recognized professionals as well as more junior staff.

(c) Marshall relevant resources from within government, not just Environment Canada, to take part in a cooperative and integrated effort in the interest of the Canadian environment and the people of Canada. The ordinary process of cross-department consultation can be cumbersome, time-consuming, and may offer opportunities to thwart the decision-making process. It should be avoided.

(d) Arrange to hire temporary personnel from among qualified members of the private sector.

(e) Access existing and relevant information resources and experience world-wide.

(f) Contract with national and international agencies such as the Environmental Protection Agency in the United States and the OECD to assist in this effort.

Once the system is up and running, the effort to maintain it will be demanding and will require adequate resources, but the greatest need for competent resources will be up-front, to make the new Act operational in the shortest possible time.